Soft and Semi-soft Cheese made from Unpasteurized/Raw Milk in Canada
Bureau of Microbial Hazards, Food Directorate, Health Canada

Presented to the American Cheese Society Annual Conference
August 6, 2011 - Montreal, QC
Summary

• Background – Current Regulations
• Drivers for Change
• International Context
• Current Situation
• Moving Forward
• Stakeholder Involvement
Pasteurization

- In Canada, pasteurization is mandatory for all dairy products except cheese (F&D Regs – B.08.002.2)

- **Exceptions**
  - Cheese can be made from pasteurized milk, heat treated milk (thermized) or raw milk
    - Cheese must be stored (60 days) at 2°C and above if heat treated or raw milk is used
  - If the milk or cheese is used in products that would achieve pasteurization
  - (F&D Regulations – B08.002.2, B.08.030, B.08.044)
The *Food and Drug Regulations* (FDR) allow for the production of cheese made from unpasteurized milk if they are stored for 60 days before sale at a temperature of 2°C or more.

- Most cheeses available were hard or firm cheese
- Pathogens of concern *M. tuberculosis* and *B. abortus* were killed during storage due to a decrease in pH and Aw
- In addition, the FDR set microbiological criteria for cheese.
  - No person shall sell cheese made from an unpasteurized source if the cheese contains more than 500 *Escherichia coli* /gram of cheese or more than 1000 *Staphylococcus aureus* /gram of cheese (B.08.048 (2) of the FDR)
Drivers for Change

- A recent FD risk assessment indicates that the 60-day storage requirement mandated by the FDR for soft and semi-soft cheese made from unpasteurized milk may allow for the growth of foodborne pathogens, such as *L. monocytogenes*.

- The FDR’s current microbiological criteria for cheese made from unpasteurized milk are outdated and do not reflect the risk posed by pathogens such as *L. monocytogenes* or *E. coli* O157:H7.

- Since 2001, the CFIA has permitted imports from France of soft and semi-soft cheese made from unpasteurized milk to be sold in Canada without a 60-day storage period.

- This compliance policy is based on evidence that soft and semi-soft cheese made from raw/unpasteurized milk according to the French industry’s application of EU requirements do not present a health and safety concern.

- The EU would like this policy to be expanded to include other countries.
International Context

- Internationally, there is a range of approaches to the management of unpasteurized soft and semi-soft cheese
  - The EU permits the sale of unpasteurized cheese provided it is produced and labelled according to specified criteria.
  - New Zealand introduced new legislation in 2010 that allows certain unpasteurized milk products (those that can be produced to an acceptable level of safety) to be produced, sold, exported and imported.
  - Like NZ, Australia is proposing to categorize unpasteurized milk products according to the risk that they pose to consumers, with differing requirements depending on risk.
  - In the U.S. if soft and semi-soft cheese is made from raw milk, it must be held for 60 days at 35°F (2°C) or greater.
Current Situation

• Quebec amended its regulations in 2008 to permit the sale and production of soft and semi-soft cheese made from unpasteurized milk without a 60-day storage period of 2°C or more, provided the cheese is produced in compliance with specified standards.

  The FD has reviewed the Quebec requirements for manufacture of soft and semi-soft cheese made from unpasteurized milk and has no health and safety concerns. The regulations emphasize the mitigation of potential microbiological contamination of cheese during production.

• In 2009, using a Temporary Marketing Authorization Letter (TMAL), HC authorized a QC producer to sell a soft cheese made from unpasteurized milk that has not been stored for 60 days throughout Canada (except Newfoundland).

• There is inequity in market access. Producers from France are not required to store unpasteurized cheese for 60 days, while domestic producers and other foreign producers must comply with the storage requirement.
Health Canada has identified several elements that could be incorporated into an updated policy for soft and semi-soft cheeses made from unpasteurized milk. Possible elements, some of which would require regulatory amendments, include:

- no longer require a 60 day storage period for all soft and semi-soft cheese made from unpasteurized milk,
- establish microbiological criteria for milk used in the production of unpasteurized soft and semi-soft cheese,
- update the existing microbiological criteria for cheese,
- require record keeping to support enforcement,
- develop an education campaign for consumers,
- mandatory labelling requirements.
<table>
<thead>
<tr>
<th>Categories of cheeses</th>
<th>% moisture based on fat free content</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOFT CHEESE</td>
<td>&gt;67 and &lt;80</td>
</tr>
<tr>
<td>SEMI-SOFT CHEESE</td>
<td>&gt;62 and &lt;67</td>
</tr>
<tr>
<td>FIRM CHEESE</td>
<td>&gt;50 and &lt;62</td>
</tr>
<tr>
<td>HARD CHEESE</td>
<td>&lt;50</td>
</tr>
</tbody>
</table>

Canadian Dairy Information Centre

www.dairyinfo.gc.ca
### Proposed Microbiological Criteria – RAW MILK FOR USE IN CHEESE MAKING

<table>
<thead>
<tr>
<th>Analyses</th>
<th>n</th>
<th>c</th>
<th>M</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>S. aureus</em></td>
<td>5</td>
<td>0</td>
<td>2000/ml</td>
<td>0</td>
</tr>
<tr>
<td><em>E. coli</em> O157:H7</td>
<td>5</td>
<td>0</td>
<td>0/25 ml</td>
<td>0</td>
</tr>
<tr>
<td><em>L. monocytogenes</em></td>
<td>5</td>
<td>0</td>
<td>0/25 ml</td>
<td>0</td>
</tr>
<tr>
<td>Salmonella spp.</td>
<td>5</td>
<td>0</td>
<td>0/25 ml</td>
<td>0</td>
</tr>
</tbody>
</table>

### Proposed wording for the Regulation or the Guideline

- No person shall sell cheese made from an unpasteurized source if the raw milk used in the production of raw milk and unpasteurized milk cheese contains more than 2,000 cfu/ml of *S. aureus*; and

- No person shall sell cheese made from an unpasteurized source if the raw milk used in the production of raw milk and unpasteurized milk cheese contains any of the following foodborne pathogens in the analytical unit analyzed: *E.coli* O157:H7, *L. monocytogenes* or *Salmonella* spp.
Proposed Microbiological Criteria – Raw and Unpasteurized Milk Cheese

<table>
<thead>
<tr>
<th>Analyses</th>
<th>n</th>
<th>c</th>
<th>M</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus / g</td>
<td>5</td>
<td>2</td>
<td>1000/g</td>
<td>10000</td>
</tr>
<tr>
<td>E. coli / g</td>
<td>5</td>
<td>2</td>
<td>100/g (500?)</td>
<td>1000</td>
</tr>
<tr>
<td>E. coli O157:H7</td>
<td>5</td>
<td>0</td>
<td>0/25 g</td>
<td>0</td>
</tr>
<tr>
<td>L. monocytogenes</td>
<td>5</td>
<td>0</td>
<td>0</td>
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<td>5</td>
<td>0</td>
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<td>0</td>
</tr>
</tbody>
</table>

Proposed wording for the Regulation or the Guideline

• No person shall sell cheese made from an unpasteurized source if the raw milk cheese contains more than 100 cfu/g of generic *E. coli* or more than 1,000 cfu/ml of *S. aureus*; and

• No person shall sell cheese made from an unpasteurized source if the raw milk cheese contains any of the following foodborne pathogens in the analytical unit analyzed: *E. coli* O157:H7, *L. monocytogenes* or *Salmonella* spp.
A 3-phase consultation strategy is underway:

• **First phase:** Initial discussions with provincial Health and/or Agriculture ministries on the general and scientific considerations

• **Second phase:** Consultation with a broader range of stakeholders

• **Third phase:** Posting of the policy intent document on the Health Canada website as a consultation document
First phase: Discussions with provincial and territorial partners

• Initial discussions with provincial Health and/or Agriculture ministries

  • FPTFSC Meeting in November 2010
    – Presented Risk assessment and current status of policy development
    – Confirmed provinces interested in follow-up in-depth discussions

  • Followed-up with bilateral/semi-bilateral meetings with provincial partners - in January/February 2011. Provincial partners were asked to respond to specific questions in writing by March 1, 2011.
First phase: Discussions with provincial and territorial partners (cont.)

• The objectives of the bilateral and multilateral meetings were:

  - To discuss the findings of Health Canada’s health risk assessment of the impact of the 60-day storage period on the public health risks associated with the consumption of soft and semi-soft cheese made from raw or unpasteurized milk.
  - To discuss ways the science can be used to update HC’s policy
  - To gather and share information on the different provincial contexts and challenges
  - To present and seek input on proposed elements of a revised policy
First phase: Questions asked to provincial partners

Provincial partners were asked to answer the following questions in writing by March 1st 2011.

- What is the regulatory situation in your jurisdiction?
- Are there any manufacturers in your jurisdiction who make soft or semi-soft cheese from raw and unpasteurized milk and store it for less than 60 days? Store it for 60 days or more?
- Are there any regional concerns with the policy objectives?
- Are there any suggestions to improve the scope of the proposed policy elements?
- Are there additional policy elements which should be considered?
- Who are the stakeholder groups in your jurisdiction that should be invited to participate in the broader consultation?
What we’ve heard so far

Common themes were raised during the discussion meetings. These included:

• Questions regarding the implementation enforcement of revisions to HC’s policy and regulations on soft and semi-soft raw milk cheese, particularly with respect to non-federally registered plants;

• Concerns over the sale across Canada of soft cheese made of unpasteurized milk by a Quebec producer following the issuance of a TMAL by Health Canada;

• The need to carefully communicate information to the public distinguishing the safety of raw milk cheese as compared to raw milk;

• Questions about how these products should be labelled; and,

• Questions regarding the design of any public education campaign.
Next phases – Phases # 2 and 3

• Feedback received will help to refine potential options for next phase of consultation.

• HC is currently planning phase 2 of the consultation strategy:
  ➢ Anticipated to start in the Fall and last for three months
  ➢ Consultation will be done mostly online via a consultation document
  ➢ Gather information from a broad segment of stakeholders (e.g. industry, consumer groups)

• It is anticipated that the publication of the policy intent document on HC’s web site for consultation will occur in Spring 2012
Canadian Stakeholders come forward!

• Should you want to be notified of the date the consultation will start, please let us know by contacting the Bureau of Microbial Hazards using the contact link below:

Thank You!